JUN - 6 2001

May 29, 2001

Food and Drug Administration
Center for Devices and Radiologic Health
510(k) Document Mail Center, HFZ-401
9200 Corporate Blvd
Rockville, MD 20850

Robert J Medoff, MD
159 Ku'ukama St
Kailua, HI 96734
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Re: 510(k) Submission, supplemental information
Tension band wire forms
510(k) number: K010545

Attention:
Document Control Clerk

Dear Ms. Zimmerman:

Thank-you for the information regarding the 510(k) summary. I was unable to find the exact statute, but I did find some information on your web site that discusses the requirements of 21CFR 807.92.

I have attached the summary sheet as you have requested. Please let me know if there is any other information that you require.

Yours truly,

Robert J. Medoff, MD

510(k) SUMMARY.

510(k) nmbr: K010545

Submitted by:	TriMed, Inc. 25768 Parada Drive Valencia, California 91355 800-633-7221
Prepared by:	Robert J. Medoff, MD
Contact person:	Robert J. Medoff, MD
Date prepared:	May 29, 2001
Proprietary Name:	TriMed tension band sled
Classification Name:	Tension band wire
Common/Usual Name:	TriMed tension band wire TriMed Patellar tension band wire TriMed Olecranon tension band wire TriMed Malleolar tension band wire TriMed Ulnar Styloid tension band wire TriMed Proximal humerus tension band wire TriMed Distal humerus tension band wire TriMed Patellar sled TriMed Olecranon sled TriMed Malleolar sled TriMed Ulnar Styloid sled (other names reserved for future sites of application)

Sample Predicate Devices:

TriMed small fragment clamp and buttress pin (510(k) K951303)
Smith and Nephew Kirschner wires and Steinman pins
Zimmer Kirschner wires and Steinman pins

Class: II, Sec. 888.3040 Smooth or threaded metallic bone fixation fastener.

Classification Panel: These devices are reviewed by an orthopaedic panel (888)

Product Code: LRN

Description of the device:

The TriMed tension band sleds are double 'U' shaped wire implants that are used as an aid to fracture fixation. They are manufactured from either medical grade 316 stainless steel or medical grade titanium-vanadium-aluminum alloy and vary in diameter from .028" to .250". Detailed dimensional characteristics of the devices has been provided in enclosure 1 of the original 510(k) application.

Intended use of the Device:

The TriMed tension band sleds are intended for use as an aid to fracture healing. The implants are inserted across a fracture site and aid in stabilization of the bone fragments until bone healing occurs. They are intended to be used in conjunction with screws, washers, and/or plates of the same material. Any fracture that is applicable to the approach of tension band wiring currently being done with separate component pins and wires is a suitable indication for this single component implant.

Technological characteristics:

The TriMed tension band wires sleds have identical technical characteristics to existing pins and wires commonly in use. Sample existing implant sales literature is supplied with enclosure 5 of the original 510(k) application, and material specification sheets are supplied with enclosure 6 of the original 510(k) application.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Robert J. Medoff, M.D.
Tri-Med, Inc.
159 Ku'ukama Street
Kailua, Hawaii 96734

Re: K010545
Trade Name: TBW (Tension Band Wire)
Regulation Number: 888.3040
Regulatory Class: II
Product Codes: NDL
Dated: February 17, 2001
Received: February 23, 2001

Dear Dr. Medoff:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Page supplemental 1 of 3

510(k) Nmber: K010545

Device Name: Tension Band Wire

Indication for use:

Skeletal fractures that are amenable to the principle of tension band wiring. Typical sites of application may include but are not limited to fractures of the olecranon, patella, medial malleolus, lateral malleolus, distal ulna, distal humerus, and proximal humerus.

The decision to use a specific implant as well as the size and shape of the implant used must be based on sound medical judgement that takes into consideration factors such as the circumstances and configuration of the injury.

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Precscription use: X OR Over-the-counter Use ____
(Per 21 CFS 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010545